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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,326	02/22/2005	Mayumi Saki	506.44792X00	8611

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,326	SAKI ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in the application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 11-12 and 15, drawn to an agent for the prevention and /or treatment of asthma which comprises an oligonucleotide capable of suppressing the function of a GPCR molecule; a method for the prevention and /or treatment of asthma which comprises administering an effective amount of said oligonucleotide; and a method of using said oligonucleotide for the manufacture of an agent for the prevention and/or treatment of asthma.

Group II, claim(s) 1 and 3, drawn to an agent for the prevention and /or treatment of asthma which comprises an antibody capable of suppressing the function of a GPCR molecule.

Group III, claim(s) 1 and 4-8, drawn to an agent for the prevention and /or treatment of asthma which comprises a nitrogen-containing tricyclic compound represented by formula (I), capable of suppressing the function of a GPCR molecule.

Group IV, claim(s) 9-10, drawn to a method for the prevention and /or treatment of asthma which comprises administering an effective amount of a nitrogen-containing tricyclic compound represented by formula (I), capable of suppressing the function of a GPCR molecule.

Group V, claim(s) 11 and 13, drawn to a method for the prevention and /or treatment of asthma which comprises administering an effective amount of an antibody, capable of suppressing the function of a GPCR molecule.

Group VI, claim(s) 14, drawn to a method of using a substance capable of suppressing the function involved in signal transduction of a human GPR4 protein for the manufacture of an agent for the prevention and/or treatment of asthma.

Group VII, claim(s) 16, drawn to a method of using an antibody capable of suppressing the function of a GPCR molecule for the manufacture of an agent for the prevention and/or treatment of asthma.

37 CFR 1.475 (c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and §1.476(c)."

37 CFR 1.475 (e) states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."

In view of 37 CFR 1.475 (e), Groups I-III are considered a plurality of the inventions listed in claim 1 for example.

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (d), Group I is considered the main invention that is drawn to the first product, first mentioned in the claims of the application (i.e. an oligonucleotide) and the first recited invention drawn to other categories related thereto (i.e. a method of using the oligonucleotide for treatment and a method of using the oligonucleotide for the manufacture of an agent).

2. The claims encompass a plurality of distinct inventions exemplified by structurally distinct nucleic acid and amino acid sequences that comprise structurally distinct molecules. Because the nucleic acids have no shared structural sequences, said genes lack unity of invention. Applicant is required to choose a single, specific GPR4 nucleic acid from SEQ ID NOS: 12, 14 and 18; or a single, specific polypeptide from SEQ ID NOS 11, 13 and 17, should any of the inventions of Groups I-VII be elected for examination. The nucleic acids and their correspondingly encoded polypeptides are also structurally distinct, and the unity of invention rule does not apply to distinct gene sequences or distinct polypeptides encoded by separate genes

or alternatively spliced forms of a gene. Hence the claims encompass an improper Markush Grouping, lacking unity of invention (In *re* *>*Harnisch*<, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). This is not a species restriction requirement.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-VII, is a substance which suppresses signal-transduction related functions of a GPCR molecule for the prevention and/or treatment of asthma. Groups I-VII do not share a special technical feature over the art because Burmer et al. (U.S Patent Publication No. 2003/0113798, filed Aug. 19, 2002), discloses antibodies and molecules directed to GPCRS (paragraph [0253]) (including those disclosed in the instant application), and the use of such molecules in treating conditions that include asthma (paragraph [0366]).

Additionally, Group I-VII claims are drawn to multiple distinct products and processes of use that do not share the same inventive concept. The claimed inventions of Groups I-VII are directed to distinct goal and method steps, and thus have their own technical features. Each of the groups has a technical feature not required for the other groups. For example, the tricyclic compound, the antibody and the oligonucleotide are each structurally and functionally distinct. Further, the methods of using each agent of the invention is also distinct, requiring non-coextensive search and examination.

Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER